JUN 2 3 2000

K001299

CP Medical

836 NE 24th AVE Portland, OR 97232 (503) 232-1555 Fax (503) 230-9993
PO BOX 6724 Portland, OR 97208 e-mail CPMEDICAL@aol.com

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1999 and 21 CFR 807.92."

Applicant: C.P. Medical
836 N.E. 24th
Portland, OR 97232
Tele: (503) 232-1555
Fax: (503) 230-9993

Contact: Patrick J. Ferguson (President)
Or
Thomas R. Brammer (V.P. Manufacturing)

Date: April 9, 2000

Name of Device:
Common or Usual name: Plain or Chromic gut absorbable surgical sutures.
Classification Name: Suture, absorbable, natural

Plain and Chromic gut surgical sutures USP manufactured by C.P. Medical are equivalent to plain and chromic gut surgical sutures manufactures by Davis & Geck. These sutures are absorbable, sterile surgical sutures, composed of purified connective tissue (mostly collagen) derived from either the serosal layer of beef (bovine) or the submucosal fibrous layer of sheep (ovine) intestines.

The plain and chromic gut sutures are packaged dry or in packing fluid composed of isopropanol, triethanolamine and water, or isopropanol, sodium benzoate, diethylethanolamine and water.

C.P. Medical plain and chromic gut surgical sutures are sterilized by gamma irradiation or ethylene oxide.

Plain and chromic gut surgical sutures USP are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Testing of suture diameter, suture length, knot pull tensile strength and needle attachment strength according to methods outlines in USP 24 demonstrates C.P. Medical plain and chromic gut surgical sutures meet or exceed USP specifications and are equivalent in terms of the above parameters to plain and chromic gut surgical sutures manufactured by Davis & Geck.

Patrick J. Ferguson, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2000

Mr. Patrick J. Ferguson
President
CP Medical
836 N.E. 24th Avenue
Portland, Oregon 97232

Re: K001299
Trade Name: Plain and Chromic Gut Absorbable Surgical Suture
Regulatory Class: II
Product Code: GAL
Dated: April 24, 2000
Received: April 24, 2000

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Monday, December 11, 1989 (Vol. 54, No. 236, Pages 50737 and 50738). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Plain and Chromic Gut Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

2. This device may not be manufactured from any material other than serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacturing of the Plain and Chromic Gut Absorbable surgical suture. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed change(s).

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4595. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bachner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if known K 001299

Device Name: Plain and Chromic gut absorbable surgical suture USP

Indication for Use:

General soft tissue approximation and/or ligation, including use in opthalmic procedures, but not for use in cardiovascular and neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001299

Prescription Use: X or Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)